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EXAMINER

LAURITZEN, AMANDA L

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/748,316
Filing Date: December 30, 2003
Appellant(s): ROOSE, JEFFREY ROBERT

James D. Wood
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11 May 2009 appealing from the Office action mailed 10 December 2008.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directed affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct. Rejection of claims 1-7, 8-14, 15 and 17-21 under 35 U.S.C. 101 as being directed to nonstatutory subject matter has been withdrawn.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

US 2003/0216669	Lang et al.	11-2003
US 2003/0236473	Dore et al.	12-2003

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claim 18 and the drawings are objected to because the claim recites specific structure that is not depicted in the drawings. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the “articulating arm with positional gyros mounted at pivotal joints of the articulating arm” of the reference pointer must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Claim Rejections - 35 USC § 112

2. Claims 15 and 17-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 15 has been amended to include a step of “determining changes in the surface of the bone using the received positional data,” but this feature cannot be corresponded to applicant's disclosure. Examiner has identified paragraph [0049] in that positional data are disclosed to represent data regarding an articulating arm joint and that the data is further used to determine movement of the tip of *the reference pointer*, 208, in space. Using positional data to determine movement of a tip of a reference pointer in space cannot be interpreted to encompass

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determining changes in the surface of the bone as claimed and is this amendment is therefore interpreted as new matter.

New claim 21 specifies that the registration module be further configured to identify a portion of a bone remaining to be excised based upon the received positional data, but this feature is not described in applicant's specification. The disclosure apparently makes no mention of identifying regions of bone to be excised. In paragraph [0038], removal of "portions of flanges" is specified but these understood as part of the implant and not part of the bone.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Providing a reference pointer in the form of "an articulating arm with positional gyros mounted at pivotal joints of the articulating arm" is critical or essential to the practice of the invention, but it is not clear what this exactly refers to because the phraseology is not conventional in the art and the feature is not depicted in the drawings so it is therefore not enabled by the disclosure. It is not clear how one would make and/or use the invention. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claim Rejections - 35 USC § 103

3. Claims 1-7 and 8-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lang et al. (US 2003/0216669 in view of Dore et al. (2003/0236473).

Lang et al. disclose a system and method for designing a surgical guide for a joint replacement prosthesis and delineate generating a bone surface image from bone CT image data ([0092], in which the bone surface image is a topographical map). Additionally disclosed is a method for superimposing an image of a prosthetic implant on a bone surface image [0028],

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[0030]. The disclosure of Lang et al includes fabrication of a surgical guide in the form of an aperture guide and/or template [0049]. Additionally a “surgical guide image” is generated [0028]. While Lang et al. disclose rapid prototyping and stereolithographic techniques, which are generally understood to include using control data from an image or image creating program, Lang et al. does not specifically address this feature. However, in the same field of endeavor, Dore et al. teach using image data to control implant construction, which results in “machine tool control data” [0016, Dore et al]. It would have been obvious to one of ordinary skill in the pertinent art at the time of invention to use image data to direct automatic construction of a prosthetic device, as taught by Dore et al.

Regarding claims 3-5 and 10-12, an intra-operative (surgical guide) image includes at least one marker [0096, Lang et al]. Lang et al. teach laser and/or cutting treatment of many materials, including polymer (resins) [0015-0016], and such processes are well known in rapid prototyping schemes.

Regarding system claims 13-14, the system of Lang et al. as modified Dore et al. is inherently capable of generating image data from an acetabulum bone and an acetabular cup and/or a femur bone and femoral stem.

4. Claims 15 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson et al. (US 2002/0147455).

Carson et al. teach generally an imaging system for tracking patient anatomy and implant prostheses. The memory ([0094] and Fig. 1) serves as a repository. A mouse [0094] serves as a pointing device/reference pointer and it is well-known to skilled artisans to use wireless pointing devices. Position and orientation image data are tracked in three dimensions [0089]. Images

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(and image data) are both registered and superimposed [0103], [0115]. The system is inherently capable for use in imaging an acetabular cup of acetabulum bone. Additionally, the system of Carson et al is specific to determining changes in the surface of the bone by, for example, determining what are termed "bone spike holes" using coordinate data [126]. Regarding claim 21, the system of Carson et al includes applying rules or intelligence to make suggestions to a surgeon as to soft tissue releases that are to be made in order to improve kinematics of the knee [0127]. This is corresponded to ligament balancing after bone resections have been made [0003]. The system is also capable of tracking the patella and resulting placement of cutting guides and the petallar trial position [0130]. Additionally, regarding claim 21, systems and processes are available to the surgeon that generate data based on position tracking and to provide cues, such as "suggesting certain bone modification steps," which would include identification of portions of the bone to be excised, as claimed [0006].

(10) Response to Arguments

Rejection of claims 1-7, 8-14, 15 and 17-21 under 35 U.S.C. 101 as being directed to nonstatutory subject matter has been withdrawn and is not addressed further.

Appellant's arguments filed 11 May 2009 have been fully considered but they are not persuasive.

Regarding rejection of claim 18 under the first paragraph of 35 U.S.C. 112 and the corresponding objection to the drawings, examiner contests concluding statements made in the appeal brief at page 6 that the structure is sufficiently shown. Recitation of a reference pointer in the form of "an articulating arm with positional gyros mounted at pivotal joints of the

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articulating arm,” as in claim 18, is understood to be a critical or essential feature of the invention. Examiner maintains that this phraseology is not conventional within the art and because the structure is not depicted in the drawings or further described in the specification it is therefore not enabled by the disclosure. Examiner maintains that it is not clear how one ordinarily skilled would make and/or use the invention.

Appellant submits that a patent to Yuan et al. fully discloses the feature claimed in claim 18, but this reference was not officially considered as it was not cited in a form PTO-1449 or equivalent for proper information disclosure. Additionally, when this reference was submitted with Appellant's remarks after the non-final Office action was issued, the patent number cited was not the correct patent number. The reference is not of record and was not considered at any point thus far in the prosecution of this application; however, examiner notes that Appellant's remarks are sufficient to establish that feature(s) of claim 18 are "known" and are properly rejected as being obvious under 35 U.S.C. 103(a).

Regarding rejection of claims 15 and 17-21 under the first paragraph of 35 U.S.C. 112 for failing to comply with the written description requirement, examiner(s) have reviewed the passages cited by Appellant as providing support for the claimed invention, but it was concluded that the claim defines features that are not within the scope of what is disclosed as the invention, such as “determining changes in the surface of the bone using the received positional data” (claim 15), and “an articulating arm with positional gyros mounted at pivotal joints of the articulating arm” (claim 18). At least the above-referenced claim features are neither explicit nor implicit from the cited paragraph(s) directed to a registration module. The feature of identifying changes in a bone surface based on positional data is not encompassed by the cited description,

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nor is support to be found anywhere else in the specification; therefore, the rejection of claims 15 and 17-21 under the first paragraph of 35 U.S.C. 112 is maintained.

Appellant's remarks regarding rejection of claims 1-7 and 8-14 based upon the combination of Lang in view of Dore have been fully considered but they are not persuasive. Appellant has stated that examiner has mischaracterized the Lang reference because portions were cited that are relevant for fabrication of prosthetic devices; however, it is noted that Lang is additionally directed to fabrication of aperture guides and template devices, as in [0048]-[0049], as well as surgical tools having surfaces "matching the geometry of an articular surface of the joint," including aperture(s) through which drills are guided, as in [0046]. Surgical guide images are generated, as in [0028]. Anatomic models are generated with the aid of anatomical imaging, as in [0062], the anatomic models themselves being encompassed by "surgical guide" as claimed. Anatomical imaging systems appropriate for generation of surgical guide images are disclosed at [0067]. Details of how these images are use to guide surgery are disclosed at [0028]. Imaging is used to guide surgery at [0085]-[0087] to assess the surface contour of the region that is to be operated.

A mathematical model of the topographical map is generated to determine the ideal surface, as in [0092]. Physical models of the surgical site are created as disclosed at [0100]-[0103], with rapid prototyping (the prototype itself qualifying as a "surgical guide" as claimed) detailed at [0109]. In determining the size of the defect to be repaired and modeling it physically, as in [0102], it is understood that surgical guide images of the region of interest are used. The machine tooling, rapid-prototyping and stereolithography techniques effective for

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creating customized surgical implements are understood to include input of control data, but this is not expressly detailed in Lang; however Dore is relied upon to teach this feature.

The description of a guide as cited from appellant's specification is not the interpretation of the claimed "surgical guide." The specification does not limit to a special definition and, accordingly, the terms are given their broadest, reasonable interpretation within the art. Thus, the surgical guide of the claims has been likened to any one of the guiding tools that are generated to aid the surgeon during or before the procedure, such as the surgical tool with a drill guide, and the physical models of the surgical area determined from pre-operative images and the prototypes created to prepare the surgeon for the procedure. Each of these is understood to include input of control data from the surgical guide image, especially in the case of rapid-prototyping of the surgical site, as in [0109], even though the disclosure of Lang is silent to this feature.

Dore et al. teach where Lang is silent; specifically, using image data to as control data for generation of a prototype or replica of the body part to be operated on (the replica being a "surgical guide"), as disclosed in the abstract and "machine control data" as disclosed at [0016]. The method and system of Dore et al. is effective for manufacture of replicas of body parts (interpreted as physical models or "surgical guides") as well as creation of implants, according to the distinction set forth in the abstract.

As to the "marker slot" of claim 3, it is understood that the surgical guide images cited in Lang et al. include various designations on the image, any of which is encompassed by an incorporated marker slot. For example, the highlighting of areas within the image to indicate poor alignment, as disclosed in Lang et al. at [0028] would constitute incorporation of a marker

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slot into an image. The markers disclosed at [0096] in Lang et al. that include “actual linear measurements” and “different colors corresponding to different amounts of deformation” are also interpreted as “marker slots.” The portion(s) of Appellant's disclosure do not prescribe an exclusive special definition for the phrase “marker slot” and therefore the claimed term(s) were given their broadest, reasonable interpretation. This interpretation reasonably includes any sort of marker, tick, or designation incorporated in the image. The portions of the Lang reference recited here and in the original rejection are relevant.

Remarks relevant to method claim 1 are relevant for corresponding system claim 8. The surgical guide is encompassed by the physical model and/or rapid prototype(s) developed with the aid of the surgical guide image. While the rapid prototyping and machining methods disclosed in Lang et al. at [0109] are understood to necessarily include input data, the reference is silent to this detail. Therefore Dore et al. was relied upon to teach this feature. The same rationale to incorporate the teachings of Dore et al. for claim 1 are applicable to claim 8, and the same portions of Dore cited are relevant.

As to claim 10, the same portion(s) of Lang et al. cited as relevant to claim 3 to address incorporation of a “marker slot” (including how this feature has been interpreted) into a surgical guide image are relevant.

Appellant's remarks with respect to the obviousness rejection of claims 15 and 17-21 in view of Carson have been fully considered but they are not persuasive.

The standard mouse of Carson is understood to be encompassed by the claimed “reference pointer” and is capable of providing positional data relevant to a surgical site, as a

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capability is described in which the anatomy is tracked with the computer system, as in the abstract. The mouse is understood to be useful for performing the functions of registration, navigation and tracking that are disclosed capabilities for the system of Carson, also appearing in the abstract. The reference pointer of Carson, in the form of a mouse, is understood to be capable of providing positional data, as positional data are embedded in registration, navigation and tracking features. Additionally, registration is performed in three dimensions in the system of Carson, as in [0002]. The registration module of Carson is in fact functional to reveal changes in the bone surface, by virtue of the position tracking and registration of image data along a user-defined axial coordinate system, as in [0113].

Position and orientation image data are tracked in three dimensions [0089]. A memory serves as a repository, as in [0094] and Fig. 1. Images (and image data) are both registered and superimposed [0103], [0115]. The system of Carson et al. is specific to determining changes in the surface of the bone by, for example, determining what are termed “bone spike holes” using coordinate data [126]. The bone spike data are useful for identifying changes in the surface of the bone and, it is generally understood that all features of the invention are accessed by way of the standard mouse, such that functions are user-operated.

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(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Amanda Lauritzen

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